510(k) Summary of Safety and Effectiveness for the Dimension® Creatine Kinase Flex® Reagent Cartridge (DF38) Dimension® Creatine Kinase MB Flex® Reagent Cartridge (DF32) CKI/MBI Calibrator (DC32)

AUG 29 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: K081731

B. Date of Preparation: August 21, 2008

C. Proprietary and Established Names:
Dimension® Creatine Kinase (CKI) Flex® Reagent Cartridge (DF38)
Dimension® Creatine Kinase MB (MBI) Flex® Reagent Cartridge (DF32)
CKI/MBI Calibrator (DC32)

D. Applicant:
Siemens Healthcare Diagnostics Inc., P.O. Box 6101, Newark, DE 19714-6101
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E. Regulatory Information:
Dimension® Creatine Kinase (CKI) Flex® Reagent Cartridge (DF38)
1. Regulation section: 21 CFR § 862.1215 - Creatine phosphokinase/creatine kinase or isoenzymes test system
2. Classification: Class II
3. Product Code: CGS, Nad reduction/nadh oxidation, cpk or isoenzymes
4. Panel: Clinical Chemistry

Dimension® Creatine Kinase MB (MBI) Flex® Reagent Cartridge (DF32)
1. Regulation section: 21 CFR § 862.1215 - Creatine phosphokinase/creatine kinase or isoenzymes test system
2. Classification: Class II
3. Product Code: JHS, Differential rate kinetic method, cpk or isoenzymes
4. Panel: Clinical Chemistry

CKI/MBI Calibrator (DC32)
1. Regulation section: 21 CFR § 862.1150 Calibrator
2. Classification: Class II
3. Product Code: JIX, Calibrator, Multi-Analyte Mixture
4. Panel: Clinical Chemistry

F. Predicate Devices:
Roche Diagnostic Systems Inc. CK-NAC Reagent (K834502)
Roche Diagnostic Systems Inc. CK-MB Reagent (K003158)
Roche Diagnostic Systems Inc. Calibrator for Automated Systems (K990460)
Roche Diagnostic Systems Inc. Calibrator for Automated Systems, CKMB (K003158)

G. Device Description:
Dimension® (CKI) Flex® Reagent Cartridge (DF38)
In a coupled enzyme reaction, the creatine kinase in patient samples catalyzes the transphosphorylation of phosphate from creatine phosphate to adenosine-

diphosphate (ADP) producing adenosine-triphosphate (ATP). Hexokinase (HK) phosphorylates glucose from the ATP to phosphorylate glucose. The resulting glucose-6-phosphate is oxidized by glucose-6-phosphate dehydrogenase (G-6-PDH) with the simultaneous reduction of nicotinamide adenine dinucleotide phosphate (NADP). The rate of formation of NADPH is directly proportional to the CK activity in the sample and is measured bichromatically at 340 and 540 nm.

Dimension® (MBI) Flex® Reagent Cartridge (DF32)
The activity of the CK-MM isoenzyme is inhibited by an antibody specific for the CK-M subunit. The activity of the B subunit of creatine kinase MB isoenzyme is not inhibited, and it is on this basis that CK-MB can be measured.
In an enzyme coupled reaction, creatine kinase in patient samples catalyzes the transphosphorylation of creatine phosphate to adenosine-diphosphate (ADP), producing adenosine-triphosphate (ATP). Hexokinase (HK) uses the ATP to phosphorylate glucose. The resulting glucose-6-phosphate is oxidized by glucose-6-phosphate dehydrogenase (G-6-PDH) with the simultaneous reduction of nicotinamide adenine dinucleotide phosphate (NADP) to NADPH.
The rate of formation of NADPH is measured bichromatically at 340, 540 nm and is directly proportional to CK-B activity in the sample.

CKI/MBI Calibrator (DC32)
CKI/MBI CAL is a liquid, multi-analyte, human serum albumin based product containing creatine kinase (human source) and creatine kinase MB (porcine source). The kit consists of four vials, two vials per level (2 and3) with 2.0 mL per vial. Level 1 calibrator for CKI/MBI is not included in the CKI/MBI CAL carton. Purified Water Diluent or reagent grade water is required for use as Calibrator Level 1. Description of the manufacturing, value assignment and stability testing process are provided in this submission report.

H. Intended Use:

Dimension® (CKI) Flex® Reagent Cartridge (DF38)
The CKI method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase in human serum and plasma on the Dimension® clinical chemistry system. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Dimension® (MBI) Flex® Reagent Cartridge (DF32)
The creatine kinase MB (MBI) method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB isoenzyme activity in human serum and plasma on the Dimension® clinical chemistry system. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

CKI/MBI Calibrator (DC32)
The CKI/MBI CAL is an *in vitro* diagnostic product for the calibration of the Creatine Kinase (CKI) and Creatine Kinase MB (MBI) methods on the Dimension® clinical chemistry system.

I. Substantial Equivalence Information:

The Dimension® (CKI) Flex® Reagent Cartridge (DF38), (MBI) Flex® Reagent Cartridge (DF32), and the CKI/MBI Calibrator (DC32) were compared to the Roche Diagnostic Systems Inc. predicate devices CK-NAC Reagent (K834502), CK-MB Reagent (K003158), Calibrator for Automated Systems (K990460), and Calibrator for Automated Systems, CKMB (K003158). A comparison of the important similarities and differences between the devices and the predicates is provided in the following tables:

Feature	Dimension® (CKI) Flex® Reagent Cartridge (DF38)	CK-NAC Reagent (K834502)
Intended Use	The CKI method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase in human serum and plasma on the Dimension® Clinical Chemistry System.	In vitro assay for the quantitative determination of creatine kinase (CK) in human serum and plasma on Roche automated clinical chemistry analyzers.
Device Technology (detection)	Bichromatic rate	UV Test
Measuring Range	7 – 1000 U/L	3 – 2300 U/L
Analytical Sensitivity	7 U/L	3 U/L

Feature	Dimension® (MBI) Flex® Reagent Cartridge (DF32)	CK-MB Reagent (K003158)
Intended Use	The creatine kinase MB (MBI) method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB isoenzyme activity in human serum and plasma on the Dimension® clinical chemistry system.	Immunoinhibition assay for the quantitative in vitro determination of the MB isoenzyme of creatine kinase in human serum and plasma on Roche automated clinical chemistry analyzers.
Device Technology (detection)	Bichromatic rate	Immunological UV Assay
Measuring Range	3 - 125 U/L	3 – 2300 U/L
Analytical Sensitivity	3 U/L	3 U/L

Feature	CKI/MBI Calibrator (DC32)	Calibrator for Automated Systems (K990460)	Calibrator for Automated Systems, CKMB (K003158)
Intended Use	The CKI/MBI CAL is an *in vitro* diagnostic product for the calibration of the Creatine Kinase (CKI) and Creatine Kinase MB (MBI) methods on the Dimension® clinical chemistry system.	Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheet.	C.f.a.s. (Calibrator for automated systems) CK-MB is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheet.
Analyte	Creatine kinase (human	Creatine kinase (rabbit	Creatine kinase-MM

	source) and creatine kinase-MB (porcine source)	muscle)	(human source) and CK-BB (porcine brain)
Matrix	Human serum albumin	Human serum	Human serum
Form	Liquid	Lyophilized	Lyophilized
Levels	CKI - Three levels MBI – Five levels	Two levels	Two levels

J. Conclusion:

The Dimension® (CKI) Flex® Reagent Cartridge (DF38), (MBI) Flex® Reagent Cartridge (DF32), and the CKI/MBI Calibrator (DC32) are substantially equivalent to the Roche Diagnostic Systems Inc. predicate devices CK-NAC Reagent (K834502), CK-MB Reagent (K003158), Calibrator for Automated Systems (K990460), and Calibrator for Automated Systems, CKMB (K003158). Comparative testing described in the protocol included in this submission demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Newark, DE 19714-6101

AUG 29 2008

Re: k081731
Trade/Device Name: Dimension® Creatine Kinase (CKI) Flex® Reagent Cartridge (DF38), Dimension® Creatine Kinase MB (MBI) Flex® Reagent Cartridge (DF32) CK/MBI Calibrator (DC32)
Regulation Number: 21 CFR§ 862.1215
Regulation Name: Creatine Phosphokinase/Creatine Kinase or Isoenzymes Test System
Regulatory Class: Class II
Product Code: CGS, JHS, JIX
Dated: June 17, 2008
Received: June 19, 2008

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081731

Device Name:

Dimension® (MBI) Flex® Reagent Cartridge (DF32)

Indication For Use:

The creatine kinase MB (MBI) method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB isoenzyme activity in human serum and plasma on the Dimension® clinical chemistry system. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081731

Indications for Use

510(k) Number (if known): K081731

Device Name:

Dimension® (CKI) Flex® Reagent Cartridge (DF38)

Indication For Use:

The CKI method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase in human serum and plasma on the Dimension® clinical chemistry system. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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510(k) k081731

Indications for Use

510(k) Number (if known): K081731

Device Name:

Dimension® CKI/MBI Calibrator (DC32)

Indication For Use:

The CKI/MBI CAL is an *in vitro* diagnostic product for the calibration of the Creatine Kinase (CKI) and Creatine Kinase MB (MBI) methods on the Dimension® clinical chemistry system.

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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